

AUG - 9 1996

K962119

10. SMDA Summary of Safety and Effectiveness - "510(k) Summary"

A. Submitter Information

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B. Device Identification

Common/Usual Name: Manual Detachable Surgical Instruments
Proprietary Name: "Re-New" Laparoscopic Instruments

C. Identification of Predicate Device(s)

The "Re-New" Laparoscopic Instruments are substantially equivalent to their predicate, "Quick Switch" (K932648, previously cleared and currently marketed).

D. Device Description

The Re-New" Laparoscopic Scissors are surgical instruments used to cut and dissect various abdominal tissue for use in endoscopic, including laparoscopic, surgical procedures. The product line includes reusable common handles that can be easily attached and detached from a series of surgical tips available, which include :

- disposable tips, and
- reusable tips.

The tip assembly is designed with a proprietary double thread, which permits simple and reliable attachment and detachment of the desired tip to the shaft of the handle/shaft component. Tip configurations include:

- Metzenbaum,
- Mini,
- Hook,
- Endocut, and,
- Micro.

E. Substantial Equivalence

The technical characteristics of the "Re-New" Laparoscopic Instruments are almost identical to those of the Microline "Quick Switch". Refer to Table A for a comparison with their predicate. Differences that exist between these devices relating to technical specifications, materials, and physical appearance do not affect the relative safety or effectiveness of the "Re-New" relative to its predicate.

The "Quick Switch" and "Re-New" are intended for use in endoscopic, including laparoscopic surgical procedures where instruments are introduced into the body through a cannula .

Table A
Comparison Table: Manual Detachable Surgical Instruments

<u>Manufacturer:</u>	<u>Model</u>	<u>K-Number</u>	<u>Class</u>	<u>Handle/Shaft:</u>	<u>Length (cm)</u>	<u>Disposable</u>	<u>Reusable</u>	<u>Diameter (mm)</u>	<u>Reusable Handles</u>	<u>Flushing Port for Cleaning</u>	<u>Tips:</u>	<u>Clinicals:</u>	<u>Clinical Claims</u>
Microline, Inc.	"Quick-Switch"	K932648	II		32			5	Yes	Yes	Scissors Standard Tips	Endoscopic (inclusive of laparoscopic) Surgical Procedures	Endoscopic (inclusive of laparoscopic) Surgical Procedures
Microline, Inc.	"Re-New"		Request II		34.42			5	Yes	Yes	Scissors Standard Tips	Endoscopic (inclusive of laparoscopic) Surgical Procedures	Endoscopic (inclusive of laparoscopic) Surgical Procedures